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10/596,278	06/07/2006	HeeYoung Lee	1114.005	4817

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EXAMINER	
SU, SUSAN SHAN	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,278	LEE, HEEYOUNG	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments filed December 15, 2008 have been fully considered but they are not persuasive. Although Applicant is correct in that Herrig does not teach liposuction or lipoinjection, it should be noted that liposuction or lipoinjection was not positively claimed in independent claim 1. The intended use language of the apparatus for liposuction and lipoinjection, as in Claims 2-3, does not structurally distinguish the claimed invention from that of prior art (which also teaches a pump, centrifugal device, and controller), suggesting that the liposuction/lipoinjection processes are not dependent on the structure of the apparatus. Since the prior art device comprises substantially the same structures as the claimed invention, it is held to be capable of performing the intended operations of the claimed apparatus.

2. Furthermore, the invention of Herrig teaches an integrated system for withdrawing body tissue (blood, which includes blood cells) from the body, centrifuging the tissue, and then returning parts of the withdrawn tissue to the patient. Conceptually, this is the same as the instant invention for withdrawing adipose tissues, centrifuging the tissue, and then returning the tissues to the patient. It is therefore not hard to see that one skilled in the art would have integrated the multiple steps in liposuction/lipoinjection into one integrated system similar to that for plasmapheresis systems so that all the components needed for the liposuction/lipoinjection procedure can be in one place.

Applicant also argues that the combination of art for Claims 4-7 teaches a series of lines and valves for directing blood to and from the centrifugal device (Herrig in

particular). It should be noted that although not expressly described, the pump in Herrig is shown to be directly connected to an external unit 16 via tubing 30, therefore a change in the pump speed/pressure will be conveyed through the tubing to the external unit.

3. Applicant pointed out that the Examiner misinterpreted the external unit of the instant invention to be the same as the drive unit of Schenck (US 5,431,620). The Examiner agrees that Schenck does not teach an external unit (a fat injection unit) as described in the Applicant's disclosure and withdraws the rejection under Schenck but is making a new ground of rejection in view of Herrig. In this Office Action, the Examiner interprets the external unit to be a temporary tissue storage reservoir, one where body tissues are temporarily held before being transferred to the centrifuge and where centrifuged body tissues will be held just prior to injection back into the patient.

Applicant further indicated that Alchas (US 5,035,708) teaches depositing centrifuged tissue in a graft, which is not obvious or anticipatory of the claimed "subcutaneous fat layers." The Examiner withdraws the rejection under Alchas. However, upon further consideration, a new ground(s) of rejection is made in view of Brannon (US 2003/0158513).

Status of Claims

Claims 1-7 are pending, wherein independent claims 1 & 4 have been amended. All claims are examined on the merits.

Drawings

4. Amendments to Fig. 1 of the Drawings are acknowledged.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrig (US 5,478,479) in view of Schenck et al. (US 5,431,620, "Schenck"), Latham Jr. (US 4,086,924, “Latham”) and Robinson et al. (US 5,242,384, “Robinson”).

With regard to Claim 1, Herrig teaches a centrifuge comprising a centrifugal device having a rotor (all centrifuge has a rotor), a chamber (internal space within the centrifuge), a drive unit (23), a power supply (any centrifuge would have a power supply), further comprising:

a pump device (P) for vacuum and compression, and valves (V_1-V_3) connected to the pump and adapted to be opened or closed to selectively perform vacuum or compression, the pump device being controlled by the controller to selectively perform vacuum or compression (Col. 3 lines 33-

34 where "into and out of centrifuge bowl" suggests vacuum/blood-draw or compression/blood-injection as felt by the patient);

a connector (via tubing 30) to connect the pump device with an external unit (16) for performing vacuum and compression, the external unit integral with the centrifugal device (via the connector tubing 30);

wherein the centrifuge operates to sequentially perform vacuum, centrifugation, and compression (see Fig. 3).

Herrig does not teach that the centrifugal device has buckets, a controller to control the drive unit, a case having a door to open or close the chamber of the centrifugal device, that the pump is an air pump, or that the controller selectively operates a drive unit in addition to the pump device.

Schenck teaches a centrifugal device that has buckets and a case having a door to open or close the chamber of the centrifugal device.

Latham teaches a controller that controls the drive unit of a centrifuge and the pump in a plasmapheresis system.

Robinson teaches an air pump (see Abstract) used in an extracorporeal system for drawing body tissues out of the body and for returning the body tissues to the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Herrig with Schenck, Latham, and Robinson for the purpose of integrating the different parts of a surgical procedure into one unit. After the modification, the connector can be formed at the side of the case and the air pump can be mounted on the case since rearranging essential working parts requires only routine

skills in the art and one of ordinary skills would want to put the connector and the air pump on the case for easier transport of the entire system.

With regard to Claim 2, Herrig, Schenck, and Latham do not expressly teach pressure adjustors. However, Herrig does teach that the pump is capable of operating at a variety of speeds. The pressure generated by a pump functioning at different speeds would accordingly be dependent and correlated to the speed of the air pump, e.g. higher the speed higher the pressure exerted on the conduit leading from the pump. The pump rotating in one direction would generate vacuum that pulls body tissues away from the patient and in an opposite direction would generate compression that pushes centrifuged body tissues back into the patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Herrig, Schenck, and Latham for the purpose of safely controlling the rate at which body tissues are removed or returned. The claim language "for allowing liposuction and lipoinjection processes to be performed at a constant pressure" is held to be intended use for the centrifuge. Since the combination of Herrig, Schenck, and Latham is capable of adjusting the level of pressure in the system, it is capable of carrying out a liposuction/lipoinjection procedure at a constant pressure as intended by the Applicant.

With regard to Claim 3, Latham also teaches speed adjustors (56) adapted to adjust the flow rate of air in consideration of the skill of an operator. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Herrig and Schenck with Latham for the purpose of controlling the pump speed for a safe surgical procedure. After the modification, the speed adjustors can be placed in press lines

between the air pump and the connector of the case because one skilled in the art would want to keep all working parts in the same unit. The claim language "in consideration of the skill of an operator and body regions where liposuction and lipoinjection operations are performed" is deemed to be intended use language and the combination of Herrig, Schenck, and Latham is capable of being applied to liposuction/lipoinjection because the system teaches drawing body tissues, centrifuging the tissues, and returning the tissues to the patient.

8. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brannon et al. (US 2003/0158513) in view of Herrig, Schenck, Latham, and Robinson.

With regard to Claim 4 & 6-7, Brannon teaches a method of performing liposuction using a centrifuge comprising:

performing a liposuction process by inserting a cannula into an incision and applying vacuum for liposuction ([0009]);

performing a centrifugation process by mounting a syringe, that is filled with suctioned fat, and operating the centrifugal device to centrifugally obtain pure fat ([0009]);

performing a lipoinjection process by allowing the pure fat to be injected into subcutaneous fat layers.

Brannon does not teach the specific features of the centrifuge, first to fifth valves, the foot switches, or opening valves to equilibrate pressure inside and outside the system before and after the vacuum/compression processes.

Herrig, Schenck, Latham, and Robinson combine to teach the features of the centrifuge and that the centrifuge operates to sequentially perform vacuum, centrifugation, and compression except the number of valves and a plurality of foot switches. It is conventional knowledge to add more valves when there are more conduits involved, therefore mere duplication of essential working features does not make the instant claimed feature of five valves patentably distinct from prior art. Herrig teaches that the multiple valves (V_1-V_3) are remotely controlled (Col. 4 lines 40-46) but is mute to the specific means of control. Nevertheless, it should be understood that one skilled in the art would know to implement one of a variety of commercially available electrical or manual switches (button switches, foot switches, etc.). In the instant case, since the operator of the system typically would have both hands occupied using the liposuction/lipoinjection catheter, it would be more desirable to use a foot switch to control the valves and subsequently the fluid flow (see, for example, Taufig US 2003/0167053 for teaching of employing a foot switch in a liposuction procedure).

Herrig also teaches opening and closing the valves along with activating or deactivating the pump (Col. 4 lines 59-65). It would require only routine skills in the art to program the controller so that the pumps and valves are operated in a way to aspire or inject the tissue, e.g. first foot switch corresponds to liposuction by opening and closing the necessary valves that generates vacuum in the conduit where adipose tissues are being drawn.

Equilibrating the pressure inside and outside conduits is a common practice in the medical arts since operators understand that air is highly compressible. When a

closed conduit is not "purged" of air, it may lead to errors in the amount of materials/tissues being delivered or aspirated and the speed at which the materials/tissues move within the conduit. Such results can pose serious danger to a patient; therefore one skilled in the art would have known to open valves inside a closed circuit to allow the air pressure to equilibrate, especially when the same closed circuit is used for both vacuum and compression.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brannon with Herrig, Schenck, Latham, and Robinson for the purpose of streamlining the procedures of liposuction and lipoinjection by having all necessary equipment in one unit.

With regard to Claim 5, Herrig further teaches preventing spillage by slowing down the pump based on optical sensors that detect a certain signal (Col. 6 line 15-19). It would be obvious to one skilled in the art that safety measures such as this should be employed in the system claimed by the Applicant so that either the suction or injection procedure would not be done at a rate that can cause danger or discomfort to the patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brannon with Herrig, Schenck, Latham, and Robinson for the purpose of safely operating a device inside an operating room.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761